

**UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK**

ALLELE BIOTECHNOLOGY AND  
PHARMACEUTICALS, INC.,

Plaintiff,

v.

REGENERON PHARMACEUTICALS, INC.,

Defendant.

Case No. 7:20-cv-08255 (PMH) (AEK)

**STIPULATION AND ORDER TO NARROW THE CASE**

Plaintiff Allele Biotechnology and Pharmaceuticals, Inc. (“Allele”) and Defendant Regeneron Pharmaceuticals, Inc. (“Regeneron”) (collectively, “the Parties”), through their respective undersigned counsel, submit this Stipulation to Narrow the Case.

1. Allele brought this case, asserting that Regeneron has infringed claims 1-5 (“Asserted Claims”) of U.S. Patent No. 10,221,221 (“the ’221 Patent”).

2. Regeneron has asserted a number of defenses and counterclaims.

3. On December 5, 2022, this Court entered its Claim Construction Order (Dkt. 119) which, in addition to construing certain claim terms, addressed Regeneron’s indefiniteness defense.

4. The Court adopted Allele’s proposed construction for the term “isolated,” construing it to mean “the protein is present in other than its natural environment.” *See* Dkt. 119 at 11. Regeneron had proposed a different construction, namely “the protein is separated from its natural environment.” *Id.* Regeneron respectfully maintains that the Court should have adopted Regeneron’s proposed construction of this term. Under Regeneron’s proposed construction, its

position is that it did not infringe, because it never used a protein that had been separated from its natural environment.

5. The Court declined to construe the terms “monomeric or dimeric LanYFP fluorescent protein” (Claims 1, 4, and 5) and “monomeric polypeptide” (Claim 3), finding that those terms should have their plain and ordinary meanings. *Id.* at 11. Regeneron, however, proposed that “monomeric or dimeric LanYFP fluorescent protein” be construed to mean “monomeric or dimeric green/yellow fluorescent protein that has improved extinction coefficient, quantum yield, and brightness compared to mCitrine” and “monomeric polypeptide” be construed to mean “monomeric polypeptide that has improved extinction coefficient, quantum yield, and brightness compared to mCitrine.” It is Regeneron’s position that, under its proposed construction, Allele’s Asserted Claims functionally claim a broad genus without satisfying the requirements of 35 U.S.C. § 112 (enablement and written description). Regeneron respectfully maintains that the Court should have adopted Regeneron’s proposed constructions of these terms, and that each Asserted Claim is invalid under Regeneron’s proposed constructions.

6. Furthermore, the Court rejected Regeneron’s contention that the Asserted Claims are invalid as indefinite because of the term “non-naturally occurring.” *See id.* at 14. The Court instead construed this term to mean “different in amino acid sequence from a yellow/green fluorescent protein of the species *Branchiostoma lanceolatum* that is found ‘as is’ in nature.” *See id.* at 14. Regeneron maintains that the Asserted Claims are invalid due to this term’s indefiniteness.

7. The parties wish to narrow the issues in dispute and have reached agreement on the issues set forth below.

8. Specifically, based on this Court's Claim Construction Order, the parties stipulate that the Asserted Claims of the '221 Patent are valid and that any of Regeneron's accused activities not shown to be protected by the safe harbor of 35 U.S.C. § 271(e)(1) infringed the Asserted Claims of the '221 Patent.

9. Accordingly, Regeneron consents to the entry of judgment in this action that the Asserted Claims of the '221 Patent have not been proven invalid or unenforceable.

10. Regeneron reserves the right to contest that any infringement of the Asserted Claims of the '221 Patent was willful.

11. The Parties stipulate and agree that Regeneron reserves the right to appeal the Court's Claim Construction Order, including, but not limited to, its ruling on indefiniteness, which the Parties and Court agree was a final adjudication of Regeneron's indefiniteness defense. If any aspect of the Claim Construction Order is reversed or modified by the U.S. Court of Appeals for the Federal Circuit in a manner that vacates or reverses the judgment of this Court, then Regeneron shall have the right to contest infringement and/or validity on remand, and Allele shall have the right to assert infringement and contest any claim of invalidity or unenforceability of the Asserted Claims of the '221 Patent on remand.

12. The Parties stipulate and agree that this case shall proceed solely on the issues of (1) Regeneron's § 271(e)(1) safe harbor defense, (2) whether any of Regeneron's infringement was willful, and (3) damages. To the extent that this case proceeds to trial, the jury will be informed that the parties have stipulated to Regeneron's liability, except insofar as any of Regeneron's accused activities are protected by 35 U.S.C. § 271(e). Nothing in this stipulation shall prevent either party from seeking to prevent or limit the presentation of any of these three issues at trial, whether by summary judgment, *Daubert* motion, motion in limine, or otherwise.

13. The Parties shall bear their own costs and fees on the issues that have been resolved or dismissed pursuant to this stipulation.

**PURSUANT TO STIPULATION, IT IS SO ORDERED.**

DATED: White Plains, New York  
September 18, 2023



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PHILIP M. HALPERN  
UNITED STATES DISTRICT JUDGE

Dated: September 15, 2023

Respectfully Submitted,

PERKINS COIE LLP

LATHAM & WATKINS LLP

/s/ Christopher Hanewicz (with permission)<sup>1</sup>

/s/ Michelle L. Ernst

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<sup>1</sup> Electronic signatures are used with consent in accordance with Rule 8.5(b) of the Court's ECF Rules and Instructions.

<sup>2</sup> Not admitted to practice in California. Admitted to practice in Washington, DC.